

time-period from March 24, 2011 through January 25, 2013.

3. MD Anderson objected to OCR's authority to impose the CMP and appealed the NPD to an Administrative Law Judge ("ALJ"), pursuant to the agency's administrative review process. The ALJ granted summary judgment in favor of the OCR, and in doing so, refused to consider certain arguments and defenses MD Anderson raised, claiming it was outside the authority of an ALJ to consider them. MD Anderson appealed the ALJ's decision to the Departmental Appeals Board ("DAB") pursuant to 45 C.F.R. § 160.548(a). The DAB affirmed the ALJ's decision and likewise refused to consider certain of MD Anderson's arguments and defenses, claiming that it was outside the authority of the DAB to consider them. These arguments and defenses include: (1) the Secretary exceeded his statutory authority under 42 U.S.C. § 1320d-5 in assessing a CMP against MD Anderson as the statute does not allow a CMP to be assessed against States or state agencies; (2) the Secretary exceeded his statutory authority in issuing a CMP greater than the statutory caps provided for in 42 U.S.C. § 1320d-5; and (3) the CMP is excessive in violation of the Eighth Amendment to the U.S. Constitution.¹ The DAB's decision represents final agency action of the Secretary in seeking to issue and impose the CMP against MD Anderson.

4. MD Anderson now seeks declaratory and injunctive relief from this Court, as set forth below.

PARTIES

5. Plaintiff MD Anderson is a part of The University of Texas System and is an

¹ In refusing to address these grounds, the DAB explained that "appellant 'is free to make [its] *ultra vires* argument to a court.'" DAB Decision 2927, at 9; *see also id.* at 7 ("The ALJ...concluded he had no authority to address MDA's arguments that the regulations were in conflict with the statute or permitted penalties that were unconstitutionally excessive."); *id.* at 9 ("We accordingly do not address these arguments asking us to ignore or declare regulations invalid....").

agency of the State of Texas. *See* TEX. GOV'T CODE §§ 441.101(3), 572.002(10)(B), 556.001(2)(B). MD Anderson is an academic and research institution of higher learning and comprehensive cancer center dedicated to cancer treatment, education, and research. MD Anderson was one of the first three federally-recognized comprehensive cancer centers designated by the National Cancer Institute, pursuant to the National Cancer Act of 1971, in the United States.

6. Defendant Alex M. Azar II is the Secretary of the Department. The Secretary is sued in his official capacity. References to the Secretary in this Complaint are meant to refer to him, his subordinate agencies, and officials, and to his official predecessors or successors as context requires.

JURISDICTION AND VENUE

7. Jurisdiction is proper in this Court pursuant to 28 U.S.C. § 1331 as this matter arises under the Constitution and laws of the United States. Consistent with 28 U.S.C. § 1331, jurisdiction to issue the relief sought by MD Anderson is proper under (1) the Administrative Procedure Act (“APA”), 5 U.S.C. §§ 701-706; *see also Trudeau v. Fed. Trade Comm’n*, 456 F.3d 178, 185 (D.C. Cir. 2006); and (2) the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

8. Jurisdiction to issue the relief sought is further proper in this Court because the Secretary’s agency action complained of, including the regulations at issue, are *ultra vires* of his statutory and Constitutional authority. *See Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682, 689-90 (1949); *City of Arlington, Tex. v. F.C.C.*, 569 U.S. 290, 297 (2013); *Exxon Chemicals Am. v. Chao*, 298 F.3d 464, 467 (5th Cir. 2002).

9. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(e) because a substantial part of the events or omissions giving rise to this action occurred within the Southern District of Texas and because MD Anderson resides within the Southern District of

Texas and no real property is involved in this action.

10. This Court is authorized to grant declaratory and injunctive relief pursuant to 28 U.S.C. § 2201 (Declaratory Judgment Act), 28 U.S.C. § 2202 (injunctive relief), and 5 U.S.C. §§ 701 - 706 (authority to hold agency action unlawful and set aside agency action).

STATUTORY AND REGULATORY BACKGROUND

I. HIPAA

11. In 1996, Congress enacted the Health Insurance Portability and Accountability Act (“HIPAA”), which, among other things, required the Department to create rules, within its statutorily prescribed limits and authority, aimed at facilitating the efficient and secure dissemination of protected health information in a manner that maintains information privacy. 42 U.S.C. § 1320d-2 – 1320d-8. Pursuant to this statutory authority, the Department adopted formal rules establishing certain security standards and regulations for the protection of PHI and ePHI. 45 C.F.R. Part 160 and Part 164, Subparts A and E (“Privacy Rule”); 45 C.F.R. Part 160 and Part 164, Subparts A and C (“Security Rule”).

II. Statutory Definition of “Person” Under HIPAA

12. In issuing the CMP against MD Anderson, the OCR claimed authority under 42 U.S.C. § 1320d-5 of HIPAA. Section 1320d-5 only authorizes the issuance of a CMP against a “person”, as defined in 42 U.S.C. § 1301(a)(3). *See* 42 U.S.C. § 1320d-5. The statutory definition of “person”, as defined in 42 U.S.C. § 1301(a)(3), states:

The term ‘person’ means an individual, a trust or estate, a partnership, or a corporation.

42 U.S.C. § 1301(a)(3). The definition of “person” in HIPAA excludes the States and state agencies. Indeed, the statute includes a separate definition of “States.” *See* 42 U.S.C. § 1301(a)(1). The OCR acknowledges that this is the applicable statutory definition. *See* 70 Fed. Reg. 20224,

20227 (Apr. 18, 2005) (stating “[t]he statutory definition of a ‘person’ that would otherwise apply to the HIPAA provisions is found in section 1101(3) of the Act. That section, which has been in the Act since it was originally enacted in 1935, defines a person as ‘an individual, a trust or estate, a partnership, or a corporation.’”).

13. Despite the statutorily prescribed limits of 42 U.S.C. § 1320d-5 and 42 U.S.C. § 1301(a)(3), the Secretary, without Congressional authority, expanded the definition and scope of the term “person” in regulation 45 C.F.R. § 160.103 (for purposes of issuing a CMP under HIPAA) to include the States and state agencies. 45 C.F.R. 160.103 defines “person” as “a natural person, trust or estate, partnership, corporation, professional association or corporation, *or other entity, public or private.*” (emphasis added).

III. Statutory Caps on CMPs under HIPAA

14. Congress adopted the civil-penalty scheme for HIPAA in § 1320d-5, as part of the HITECH Act in 2009. Section 1320d-5 of the statute provides four tiers of penalties, which are based on the three distinct levels of culpability: (1) did not know (\$100 per violation with \$25,000 maximum per year); (2) reasonable cause (\$1,000 per violation with \$100,000 maximum per year); (3) willful neglect and corrected (\$10,000 per violation with \$250,000 maximum per year); and (4) willful neglect not corrected (\$50,000 per violation with \$1,500,000 maximum per year). 42 U.S.C. § 1320d-5(a)(1)(A)-(C).

15. For alleged “reasonable cause” violations, the statute provides that the “total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed \$100,000.” 42 U.S.C. § 1320d-5(a)(3)(B).

16. Despite the statutorily established caps on penalties under Section 1320d-5, the Secretary issued regulation 45 C.F.R. § 160.404(b) that ignores the penalty caps and seeks to establish a maximum penalty of \$1,500,000.00 per year per identical violation for all HIPAA

violations regardless of the level of culpability.

IV. Eighth Amendment of U.S. Constitution

17. A CMP under 42 U.S.C. § 1320d-5 is punitive and is, thus, subject to examination under and limitation by the Excessive Fines Clause of the United States Constitution. *See* U.S. Const. amend. VIII. The Eighth Amendment of the U.S. Constitution provides that: “[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted.” “The Excessive Fines Clause [of the Eight Amendment] . . . ‘limits the government’s power to extract payments, whether in cash or in kind, as punishment for some offense.’” *U.S. v. Bajakajian*, 524 U.S. 321, 328 (1998).

FACTS SPECIFIC TO THIS CASE

18. The declaratory judgment and injunctive relief that MD Anderson seeks relate to the CMP that the Secretary imposed on MD Anderson for (1) alleged violations of an optional encryption standard, (2) the theft of a laptop in a home burglary, and (3) the loss of two USB drives; all of which MD Anderson self-reported to the OCR. Following each instance, (1) there has been no evidence that any information from the devices was ever accessed or disclosed; and (2) no individuals whose information was contained on the devices has been harmed by the theft or loss of the devices. In pursuing the CMP, the OCR has agreed that no harm to any patients occurred.

19. The first CMP imposed by the Secretary is in the amount of \$1,348,000 for alleged “addressable” (“optional”) encryption violations between March 24, 2011 and January 25, 2013. During the time calculated for this alleged violation, MD Anderson had appropriate policies in place and pursued encryption efforts in light of available technologies and considerations for uninterrupted, critical patient care. The Secretary calculated this CMP at \$2,000 a day and at a culpability level of “reasonable cause.”

20. The second CMP imposed by the Secretary is in the amount of \$1,500,000 for two alleged disclosure violations in 2012 related to a laptop stolen from a researchers secured home and a USB drive misplaced by a student-researcher. There is no indication or evidence of harm to any individuals due to these alleged violations, nor is there any indication that information on either device has been accessed, viewed, or used by another person. The Secretary calculated this CMP at \$1,000 for each patient's electronic protected health information ("ePHI") that was on the drives and at a culpability level of "reasonable cause." The CMP of \$1,500,000 for this violation is the maximum amount that the OCR could impose for the two alleged incidents under any level of culpability under HIPAA, making the punishment the same as in a case in which ePHI was intentionally taken to cause harm to patients and where harm was actually incurred.

21. The third CMP imposed by the Secretary is in the amount of \$1,500,000 for one alleged disclosure violation in December 2013 related to a lost USB drive by a university researcher following the researcher's failure to use an encrypted thumb drive. This CMP involved an employee who was trained by MD Anderson on properly securing ePHI and who was furnished an encrypted USB drive by MD Anderson, although she chose not to use it. It is undisputed that the employee disregarded MD Anderson policies, the training she received, and the encrypted USB device that MD Anderson furnished to her to securely transport ePHI. The CMP of \$1,500,000 for this violation is the maximum amount that the OCR could impose under any level of culpability under HIPAA, making the punishment the same as in a case in which ePHI was intentionally taken to cause harm to patients and where harm was actually incurred.

22. The Secretary imposed a CMP of \$4,348,000 despite that (1) MD Anderson self-reported these incidents, (2) it is undisputed that there is or was no harm, and (3) the employees

acted contrary to MD Anderson policies, training, and compliance efforts, as well as ignored or refused to take advantage of the encryption technologies MD Anderson made available to them.

23. MD Anderson appealed the CMP to an ALJ who refused to consider certain arguments and defenses MD Anderson raised, claiming it was outside his authority. MD Anderson appealed the ALJ's decision to the DAB, who likewise refused to consider certain of MD Anderson's arguments and defenses, also claiming that such issues were outside the authority of the DAB.

24. On April 8, 2019, MD Anderson filed a Petition for Review with the Fifth Circuit Court of Appeals under Rule 15 of the Federal Rules of Appellate Procedure to seek judicial review of the DAB's decision. *The Univ. of Tex. MD Anderson Cancer Ctr. v HHS, No. 19-60226*. However, the DAB's refusal to address certain arguments and defenses that MD Anderson presented to the agency as part of its administrative appeal raises a question as to the proper forum for the resolution of the pending statutory and constitutional issues raised by MD Anderson, including whether the Fifth Circuit will conclude that it has jurisdiction or authority to hear the arguments and defenses in light of the DAB and ALJ's refusal to consider or rule upon them.

25. Accordingly, MD Anderson now seeks declaratory and injunctive relief from this Court to resolve the unanswered claims raised by MD Anderson that the CMP sought by the Secretary is in violation of statutory law and the Eighth Amendment of the U.S. Constitution.

CLAIMS FOR RELIEF

COUNT I: THE SECRETARY LACKS STATUTORY AUTHORITY UNDER HIPAA TO IMPOSE A CMP AGAINST A STATE AGENCY.

26. Paragraphs 1-25, inclusive, are realleged and incorporated as if fully set out herein for all purposes.

27. Section 1320d-5 of HIPAA authorizes the Secretary to impose a CMP against a “person”, as that term is defined in 42 U.S.C. § 1301(a)(3). 42 U.S.C. § 1301(a)(3) provides that “person” “means an individual, a trust or estate, a partnership, or a corporation.” The definition of “person” in 42 U.S.C. § 1301(a)(3) does not include a State or state agency.² *See Burgess v. United States*, 553 U.S. 124, 130 (2008) (“As a rule, [a] definition which declares what a term ‘means’ ... excludes any meaning that is not stated.”); *Equal Access for El Paso, Inc. v. Hawkins*, 562 F.3d 724, 727 (5th Cir. 2009) (confirming that when a statute defines what a term “means,” courts are not free to expand the statutory term beyond its express, limited text).

28. The definition of “person” in 42 U.S.C. § 1301(a)(3) also must be interpreted in light of the “longstanding...presumption that ‘person’ does not include the sovereign.” *Vermont Agency of Nat. Resources v. U.S. ex rel. Stevens*, 529 U.S. 765, 780 (2000).

29. Accordingly, the definition of “person” in 42 U.S.C. § 1301(a)(3), which is the statutory definition of “person” applicable to HIPAA, does not authorize the Secretary to impose a CMP on a state agency, such as MD Anderson. The Secretary also recognizes that this definition “would otherwise apply to the HIPAA provisions.” 70 Fed. Reg. 20224, 20227 (Apr. 18, 2005).

30. Nevertheless, the Secretary implemented a rule in 45 C.F.R. § 160.103, which defines “person” for purposes of HIPAA as including public entities, including States and state agencies. *See* 45 C.F.R. § 160.103 (“Person means a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.”).

31. The Secretary exceeded his statutory authority under Section 1320d-5 by impermissibly expanding the definition of “person” in 45 C.F.R. § 160.103 to include public

² Indeed, § 1301 provides an entirely separate definition for the term “State.” *See* 42 U.S.C. § 1301(a)(1).

entities, such as the States or state agencies, and by actually imposing a CMP on MD Anderson, a state agency, without Congressional authority.

32. Accordingly, MD Anderson seeks a judicial declaration that (1) the definition of “person” in 42 U.S.C. § 1301(a)(3), applicable to Section 1320d-5 of HIPAA, does not include the States or state agencies; (2) the Secretary’s definition of “person” in 45 C.F.R. § 160.103, which impermissibly broadens the definition of “person” to include States and state agencies, is an unlawful exercise and expansion of statutory authority that exceeds the Secretary’s prescribed powers; and (3) the Secretary’s attempt to issue a CMP against MD Anderson under 45 C.F.R. § 160.103 is an unlawful exercise and expansion of statutory authority that exceeds the Secretary’s prescribed powers.

33. To the extent any other provisions of the Secretary’s regulations incorporate or otherwise rely on the Secretary’s impermissible definition of “person” in 45 C.F.R. § 160.103, they should also be judicially declared as an unlawful exercise outside the Secretary’s authorized power. MD Anderson also seeks any injunctive relief available in relation to this statutory violation, including injunctive relief preventing the Secretary from seeking enforcement of the improper CMP against MD Anderson.

COUNT II: THE SECRETARY EXCEEDED HIS AUTHORITY BY IMPOSING A CMP BEYOND THE STATUTORY CAPS

34. Paragraphs 1-33, inclusive, are realleged and incorporated as if fully set out herein for all purposes.

35. Section 1320d-5 of HIPAA provides four statutory tiers of civil monetary penalties based on distinct levels of culpability: (i) “did not know” violations; (ii) “reasonable cause” violations; (iii) “willful neglect and corrected” violations; and (iv) “willful neglect not corrected” violations. Section 1320d-5(a)(3) provides distinct penalty amounts per violation and

distinct yearly maximums, or caps, for each tier of culpability.

36. For “reasonable cause” violations, Section 1320d-5(a)(3)(B) provides that the “total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed \$100,000.” 42 U.S.C. § 1320d-5(a)(3)(B).

37. Despite the statutory cap of \$100,000 per calendar year for “reasonable cause” violations, the Secretary ordered that MD Anderson pay a CMP totaling \$4,348,000 for the alleged violations, an amount almost 10 times more than the statutory caps.

38. To circumvent the statutory caps, the Secretary ignored the culpability-specific penalty caps in § 1320d-5(a)(3) and erroneously assigned the highest-level penalty cap of \$1,500,000 for every culpability level. *See* 45 C.F.R. § 160.404(b).

39. The Secretary’s reading of § 1320d-5 erroneously renders the culpability-specific caps in § 1320d-5(a)(3) meaningless in violation of basic statutory construction principles—that the words in a statute must be given effect and meaning and that agency action cannot overcome the plain text written by Congress.

40. MD Anderson, thus, seeks a judicial declaration that (1) the Secretary’s calculation of the CMP against MD Anderson is in excess of the statutory caps set forth in 42 U.S.C. § 1320d-5(a)(3)(B); (2) the penalty caps the Secretary set forth in regulation 45 C.F.R. § 160.404(b) are an unlawful exercise and expansion of statutory authority that exceeds the Secretary’s prescribed powers and ignores the statutory caps in Section 1320d-5 applicable to varying levels of culpability; and (3) the Secretary acted unlawfully and outside of his statutory authority in issuing and imposing a CMP against MD Anderson using the highest level of culpability penalty cap for an alleged “reasonable cause” violation.

41. MD Anderson also seeks any injunctive relief available in relation to this statutory violation, including injunctive relief preventing the Secretary from seeking enforcement of the improper CMP against MD Anderson.

COUNT III: THE SECRETARY EXCEEDED HIS AUTHORITY BY IMPOSING AN EXCESSIVE CMP IN VIOLATION OF THE EIGHTH AMENDMENT

42. Paragraphs 1-41, inclusive, are realleged and incorporated as if fully set out herein.

43. “The Excessive Fines Clause [of the Eight Amendment] . . . ‘limits the government’s power to extract payments, whether in cash or in kind, as punishment for some offense.’” *U.S. v. Bajakajian*, 524 U.S. 321, 328 (1998); *see also* U.S. Const. amend. VIII (“Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted.”).

44. “Protection against excessive punitive economic sanctions secured by the [Excessive Fines] Clause is...both ‘fundamental to our scheme of ordered liberty’ and ‘deeply rooted in this Nation’s history and tradition.’” *Timbs v. Indiana*, 139 S. Ct. 682, 689 (2019) (citation omitted).

45. “The touchstone of the constitutional inquiry under the Excessive Fines Clause is the principle of proportionality: The amount of the forfeiture must bear some relationship to the gravity of the offense that it is designed to punish.” *Bajakajian*, 524 U.S. at 334. “If the amount of the forfeiture is grossly disproportional to the gravity of the defendant’s offense, it is unconstitutional.” *Id.* at 337.

46. MD Anderson’s self-reported losses of three pieces of equipment out of tens of thousands devices, by three employees out of more than 21,000, over a two-year period cannot objectively be viewed as warranting the highest level of CMP allowable by law for any HIPAA

offense under any level of culpability. When the harm to the government (and potentially affected individuals) is \$0 and the civil penalty is \$4,348,000, the gross disproportionality of the penalty, as well as the penalty's excessiveness, is clear.

47. Accordingly, MD Anderson seeks a judicial declaration that the Secretary violated the Eighth Amendment of the Constitution and exceeded his authority by calculating and imposing a CMP that is excessive under the Constitution. MD Anderson also seeks any injunctive relief available in relation to this constitutional violation, including injunctive relief preventing the Secretary from seeking enforcement of the improper CMP against MD Anderson.

PRAYER FOR RELIEF

48. **WHEREFORE**, Plaintiff respectfully requests that this Court:

a. Declare that (1) the definition of "person" in 42 U.S.C. § 1301(a)(3), applicable to Section 1320d-5 of HIPAA, does not include the States or state agencies; (2) the Secretary's defined term "person" in 45 C.F.R. § 160.103 impermissibly broadens the definition of "person" under HIPAA in 42 U.S.C. § 1301(a)(3) to include States and state agencies and is an unlawful exercise and expansion of statutory authority that exceeds the Secretary's prescribed powers; and (3) the Secretary's attempt to issue a CMP against MD Anderson under 45 C.F.R. § 160.103 is an unlawful exercise and expansion of statutory authority that exceeds the Secretary's prescribed powers, including, among other things, that the Secretary's final action and regulation are *ultra vires* and:

- i. arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
- ii. contrary to constitutional right, power, privilege, or immunity; and
- iii. in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

b. Declare that (1) the Secretary's calculation of the CMP against MD Anderson is in excess of the statutory caps set forth in 42 U.S.C. § 1320d-5(a)(3)(B); (2) the penalty caps the Secretary promulgated in regulation 45 C.F.R. § 160.404(b) are an unlawful exercise and expansion of statutory authority that exceeds the Secretary's prescribed powers and are contrary to the statutory caps in Section 1320d-5; and (3) the Secretary acted unlawfully and outside of his statutory authority in issuing and imposing a CMP against MD Anderson using the highest level of culpability penalty cap for an alleged "reasonable cause" violation, including, among other things, that the Secretary's final action and regulation are *ultra vires* and:

- i. arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
- ii. contrary to constitutional right, power, privilege, or immunity; and
- iii. in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

c. Declare that the CMP imposed by the Secretary is excessive in violation of the Eight Amendment to the United States Constitution, including, among other things, that the Secretary's final action is *ultra vires* and:

- i. arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
- ii. contrary to constitutional right, power, privilege, or immunity;
- iii. in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; and
- iv. unsupported by substantial evidence.

d. Grant and issue a permanent injunction prohibiting the Secretary, his successors in office, his agents, employees, and all persons acting in concert with him from attempting to enforce or collect the CMP impermissibly imposed against MD Anderson;

- e. Award Plaintiff costs of the suit herein; and
- f. Grant Plaintiff any such other and further relief as the Court deems just and proper.

Dated: April 9, 2019

Respectfully submitted,

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